## REMARKS

1. Inventions I-IV (Election among the polypeptide sequences)

Paper No. 6 maintains that: "Inventions I-IV are independent and distinct, each from each other, because they are products (SEQ ID NO: 1, 3, 4 and 8) which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged." (Paper No. 6, p. 2.) Specific support for this restriction is not identified in Paper No. 6. The "products" identified in Paper No. 6 are claimed in the instant application in a Markush type claim. Applicant respectfully submits the restrictions are improper.

Claim 2, which includes SEQ ID NO: 1, 3, 4 and 8, is a Markush claim, listing the four polypeptides as members. Under MPEP § 803.02, if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not require restrictions. Moreover, it is improper to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.

Broadly speaking, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. MPEP § 803.02. Restriction of the polypeptides is improper because they are sufficiently few in number (four), they share a common utility (anti-fungal activity), and they share a substantial structural feature disclosed as being

essential to that utility (amino acid sequences Lysine-Proline-Valine at the C-terminus of the peptide).

2. Inventions I and V; II and VI; III and VII; and IV- VIII

Paper No. 6 maintains that inventions I and V, II and VI, III and VII, and IV and VIII are related as product and process of use. MPEP § 806.05(h) is the cited authority for this rejection. Under MPEP § 806.05(h), the inventions can be shown to be distinct if either or both of the following can be shown: 1) the process for using the product as claimed can be practiced with another materially different product, or 2) the product as claimed can be used in a materially different process of using that product. MPEP § 806.05(h) further states that the burden is on the Examiner to provide an example for either 1 or 2 above. In Paper No. 6, an example is given that: "In the instant case the pharmaceutical composition can be used as a protein source, or to treat infection." (Paper No. 6, pp. 2-3.) Applicant respectfully submits that this example is insufficient to support the restriction requirement.

First, the claimed and disclosed dosages for the peptide portion of the pharmaceutical composition of the instant application range in the $10^{-12}$-$10^{-4}$ M range. This equates to a *de minimis* of protein for the "protein source" identified in Paper No. 6. Although Paper No. 6 does not identify the target for this protein source, it is apparent that the peptides as disclosed and claimed would not be a suitable protein source.

Second, assuming that the peptides of the instant application were a protein source, this utility is considered a "throw away" utility and one not in compliance with 35 U.S.C. § 101. According to the Revised Interim Utility Guidelines Training Materials (RIUGTM) <http://www.uspto.gov/web/menu/utility.pdf>, throw away utilities do not meet the tests for

specific and substantial utility. (RIUGTM, p. 7.) Specifically, the RIUGTM advises that: "[U]se of any protein as an animal food supplement or a shampoo ingredient are 'throw away' utilities that would not pass muster as a specific or substantial utilities under 35 U.S.C. § 101." (*Id.*) Nor would "protein source" qualify as a well established utility. The RIUGTM states:

> Well established utility does not encompass any 'throw away' utility that one can dream up for an invention or a non-specific utility that would apply to virtually every member of a general class of materials. If this were the case...any protein would have a well established utility as a protein supplement for animal food." (*Id.* at pp. 7-8.)

The example given in Paper No. 6 is even less specific than the unacceptable utility of a protein supplement for animal food given in the RIUGTM. Applicant respectfully requests that the restriction based on this reasoning be withdrawn.

3. Unrelated inventions I as to VI-VIII; II as to V, VII, VIII; III as to V, VI, VIII; and IV as to V-VIII.

Paper No. 6 maintains that inventions I as to VI-VIII; II as to V, VII, VIII; III as to V, VI, VIII; and IV as to V-VIII are unrelated inventions if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects. (Paper No. 6, pp. 2-3.) Sections 806.04 and 808.01 of the MPEP are cited for authority. Paper No. 6 states the inventions are not disclosed as capable

of use together. Applicant respectfully traverses this restriction and offers support from the disclosure that the inventions designated in Paper No. 6 are capable of use together.[1]

First, invention I includes claims 1-19, using for the peptide portion of the pharmaceutical composition VPK-Ac-C-C-Ac-KPV (hereon SEQ ID NO: 8). Inventions V-VII are method of use claims including claims 20-28. Claim 21, included in each of the inventions designated in Paper No. 6 as inventions V-VII, specifically claim SEQ ID NO: 8 for use in the claimed method. SEQ ID NO: 8 is similarly claimed as part of the pharmaceutical composition of the invention designated as invention V in Paper No. 6. Thus, the disclosure, of which the claims form a part, support use of the designated inventions together.

Second, the disclosure supports use of the inventions together in multiple locations. On page 4 of the disclosure can be found the following disclosure: "In a preferred embodiment of the invention a therapeutically effective amount of ***one or more*** peptides selected from the group of peptides with a C-terminal sequence consisting of KPV [SEQ ID NO: 1], HFRWGKPV [SEQ ID NO: 3], and SYSMEHFRWGKPV [SEQ ID NO: 4] used in combination with a therapeutically effective amount of a fungicide...." Similar language is found on page 7 of the specification. In the examples of formulations of the claimed pharmaceutical compositions, the following is disclosed: "Set forth below are examples of various formulations of the invention. As used below the term 'Active ingredient refers to

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[1] The following remarks are made specific to the inventions identified as Invention I and VI-VIII. The remarks apply equally to inventions IV as to V-VII; II as to V, VII, VIII; and III as to V, VI, VII.

one or more peptides selected from the group of peptides with a C-terminal sequence consisting of KPV, HRFWGKPV and SYSMEHFRWGKPV." Nothing in the specification supports the assertion that the peptides cannot be used together. To the contrary, as identified above, specific support for such use is found in the specification. Applicant requests the restriction be withdrawn.

## CONCLUSION

Applicant has provisionally elected Invention I with traverse. Applicant traverses the restriction requirements of the Office Action for the reasons stated above and respectfully requests withdrawal of the restriction requirements.

Respectfully submitted,

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